

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Fallaux et al.

**Serial No.:** Not yet assigned

**Filed:** July 11, 2003

**For:** PACKAGING SYSTEMS FOR HUMAN  
RECOMBINANT ADENOVIRUS TO BE  
USED IN GENE THERAPY

**Confirmation No.:** Not yet assigned

**Examiner:** Unknown

**Group Art Unit:** Unknown

**Attorney Docket No.:** 2578-3833.9US

NOTICE OF EXPRESS MAILING

Express Mail Mailing Label Number: EV 348041909 US

Date of Deposit with USPS: July 11, 2003

Person making Deposit: Matthew Wooton

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record.

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further,

no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56 (b) exists.

Pursuant to 37 C.F.R. § 1.98(d), a copy of any patent, publication or other information listed in the Information Disclosure Statement is not required to be provided if it was previously cited by or submitted to the office in a prior application, provided that the prior application is properly identified in the statement and relied upon for an earlier filing date under 35 U.S.C. § 120.

Accordingly, no copy of information marked with a pound sign (#) is enclosed because it was previously cited or submitted to the patent office in a prior application which is properly identified above, and is relied upon for an earlier filing date. The references are as follows:

DOCUMENTS

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Issue Date</u>	<u>Inventor</u>
#4,405,712	09/20/83	Vande Woude et al.
#4,497,796	02/05/85	Salser et al.
#4,727,028	02/23/88	Santerre et al.
#4,740,463	04/26/88	Weinberg et al.
#5,190,931	03/02/93	Inouye
#5,208,149	05/04/93	Inouye
#5,378,618	01/03/95	Sternberg et al.
#5,518,913	05/21/96	Massie et al.
#5,545,522	08/13/96	Van Gelder et al.
#5,652,224	07/29/97	Wilson et al.
#5,670,488	09/23/97	Gregory et al.
#5,707,618	01/13/98	Armentano et al.
#5,753,500	05/19/98	Shenk et al.
#5,837,511	11/17/98	Falck-Pedersen et al.

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Issue Date</u>	<u>Inventor</u>
#5,851,806	12/98	Kovesdi et al.
#5,891,690	04/99	Massie
#5,919,676	07/99	Graham et al.
#5,994,106	11/30/99	Kovesdi et al.
#5,994,128	11/30/99	Fallaux et al.
#6,033,908	03/07/2000	Bout et al.
#6,040,174	03/21/2000	Imler et al.
#6,203,975	03/2001	Wilson
6,265,212	7/24/2001	Fallaux et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Date</u>	<u>Country</u>
#2,053,187	04/11/93	Canada
#WO 94/08026	04/14/94	PCT
#WO 94/11506	05/26/94	PCT
#WO 94/12649	06/09/94	PCT
#WO 94/23582	10/27/94	PCT
#WO 94/24297	10/27/94	PCT
#WO 94/26914	11/24/94	PCT
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#WO 95/00655	01/05/95	PCT
#2 707 664	01/20/95	France
#WO 95/02697	01/26/95	PCT
#95201611.1	06/15/95	EP

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#WO 95/26411	10/05/95	PCT
#WO 95/27071	10/12/95	PCT
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#WO 97/00947	01/09/97	PCT
#WO 97/04119	02/06/97	PCT
#WO 97/05255	02/13/97	PCT

Other Documents

#Amalfitano et al., "Improved adenovirus packaging cell lines to support the growth of replication-defective gene-delivery vectors", Proc. Natl. Acad. Sci. USA, 93:3352-3356, April 1996.

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#Armentano et al., "Characterization of an Adenovirus Gene Transfer Vector Containing an E4 Deletion", Human Gene Therapy, 6:1343-1353, October 1995.

#Bernards, Rene, et al., "Characterization of Cells Transformed by Ad5/Ad12 Hybrid Early Region I Plasmids", Virology, 120:422-432, 1982.

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#Brough et al., "Construction, Characterization, and Utilization of Cell Lines Which Inducibly Express the Adenovirus DNA-Binding Protein", Virology, 190:624-634, 1992.

#Brough et al., "Multiple Functions of the Adenovirus DNA-Binding Protein Are Required for Efficient Viral DNA Synthesis", Virology, 196:269-281, 1993.

#Brough et al., "Restricted changes in the adenovirus DNA-binding protein that lead to extended host range or temperature sensitive phenotypes", Journal of Virology, Vol. 55, pp. 206-212.

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#Weinberg et al., "A cell line that supports the growth of a defective early region 4 deletion mutant of human adenovirus type 2", Proc. Natl. Sci. USA, Vol. 80, pp. 5383-5386, September 1983.

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#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior applications:

Serial No.: 10/219,414

Filed: August 15, 2002

For: STOCKS OF REPLICATION DEFICIENT ADENOVIRUS, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

Applicants offer to supply any explanation or discussion of the documents which the Examiner feels is necessary or desirable and which is requested.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56 & 1.175, applicant hereby identifies the following listed copending applications naming the same inventors:

Serial No.: 08/820,479

Filed: 3/18/1997

For: METHODS AND COMPOSITIONS FOR GENETICALLY MODIFYING PRIMATE BONE MARROW CELLS



Serial No.: 08/973,560

Filed: 12/5/1997

For: P-53 BINDING PROTEIN CALLED MDMX AND ENCODING SEQUENCES FOR SAID PROTEIN

Serial No.: 09/214,836

Filed: 10/4/1999

For: MELANOMA ASSOCIATED PEPTIDE ANALOGUES AND VACCINES AGAINST MELANOMA

Serial No.: 09/332,803

Filed: 6/14/1999

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Serial No.: 09/348,354

Filed: 7/7/1999

For: CHIMAERIC ADENOVIRUSES

Serial No.: 09/381,716

Filed: 1/4/2000

For: METHODS AND COMPOSITIONS FOR GENETICALLY MODIFYING PRIMATE BONE MARROW CELLS

Serial No.: 09/444,284

Filed: 11/19/1999

For: GENE DELIVERY VECTORS PROVIDED WITH A TISSUE TROPISM FOR SMOOTH MUSCLE CELLS, AND/OR ENDOTHELIAL CELLS

Serial No.: 09/502,624

Filed: 2/11/2000

For: VECTORS AND METHODS FOR PROVIDING CELLS WITH ADDITIONAL NUCLEIC ACID MATERIAL INTEGRATED IN THE GENOME OF SAID CELLS

Serial No.: 09/506,548

Filed: 2/16/2000

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Serial No.: 09/517,898

Filed: 3/3/2000

For: MEANS AND METHODS FOR FIBROBLAST-LIKE OR MACROPHAGE-LIKE CELL TRANSDUCTION

Serial No.: 09/549,463

Filed: 4/14/2000

For: RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL

Serial No.: 09/573,740

Filed: 5/18/2000

For: SEROTYPES OF ADENOVIRUS AND USES THEREOF

Serial No.: 09/599,488

Filed: 6/23/2000

For: ADENO-ASSOCIATED VIRUS AND ADENOVIRUS CHIMERIC RECOMBINANT VIRUSES USEFUL FOR THE INTEGRATION OF FOREIGN GENETIC INFORMATION INTO CHROMOSOMAL DNA OF TARGET CELLS

Serial No.: 09/665,472

Filed: 9/20/2000

For: GENE DELIVERY VECTORS PROVIDED WITH A TISSUE TROPISM FOR DENDRITIC CELLS

Serial No.: 09/899,479

Filed: 7/5/2001

For: GENETIC MODIFICATION OF PRIMATE HEMOPOIETIC REPOPULATING STEM CELLS

Serial No.: 09/912,552

Filed: 7/23/2001

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Serial No.: 09/918,029

Filed: 7/30/2001

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Serial No.: 09/953,280  
Filed: 9/14/2001  
For: CHIMAERIC ADENOVIRUSES

Serial No.: 10/038,271  
Filed: 10/23/2001  
For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE  
USED IN GENE THERAPY

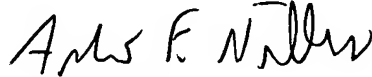
Serial No.: 10/164,076  
Filed: 6/4/2002  
For: METHODS AND COMPOSITIONS FOR GENETICALLY MODIFYING PRIMATE  
BONE MARROW CELLS

Serial No.: 10/136,139  
Filed: 5/1/2002  
For: MEANS AND METHODS FOR NUCLEIC ACID DELIVERY VEHICLE DESIGN  
AND NUCLEIC ACID TRANSFER

Serial No.: 10/196,688  
Filed: 7/15/2002  
For: ADENO-ASSOCIATED VIRUS AND ADENOVIRUS CHIMERIC RECOMBINANT  
VIRUSES USEFUL FOR THE INTEGRATION OF FOREIGN GENETIC INFORMATION  
INTO CHROMOSOMAL DNA OF TARGET CELLS

This Information Disclosure Statement is filed within three (3) months of the filing date of the above-identified application, and no certification pursuant to 37 C.F.R. § 1.97(c) or a fee pursuant to 37 C.F.R. § 1.17(p) is required.

Respectfully submitted,



Andrew F. Nilles  
Registration No. 47,825  
Attorney for Applicants  
TRASKBRITT, PC  
P. O. Box 2550  
Salt Lake City, Utah 84110-2550  
Telephone: (801) 532-1922

Date: July 11, 2003  
ACT/jml

Enclosure: Form PTO-1449

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Form PTO-1449  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <i>(Use several sheets if necessary)</i>			Docket Number (Optional) <b>3833.9US</b>		Application Number <b>Not yet assigned</b>	
			Applicant <b>Fallaux et al.</b>			
			Filing Date <b>July 11, 2003</b>		Group Art Unit <b>Unknown</b>	

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	#4,405,712	09/20/83	Vande Woude et al.			
	#4,497,796	02/05/85	Salser et al.			
	#4,727,028	02/23/88	Santerre et al.			
	#4,740,463	04/26/88	Weinberg et al.			
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	#5,208,149	05/04/93	Inouye			
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FOREIGN PATENT DOCUMENTS							
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						YES	NO
	#2,053,187	04/11/93	Canada				
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	#WO 94/11506	05/26/94	PCT				
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OTHER DOCUMENTS		(Including Author, Title, Date, Pertinent Pages, Etc.)
		#Amalfitano et al., "Improved adenovirus packaging cell lines to support the growth of replication-defective gene-delivery vectors", <u>Proc. Natl. Acad. Sci. USA</u> , 93:3352-3356, April 1996.
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		#Armentano et al., "Characterization of an Adenovirus Gene Transfer Vector Containing an E4 Deletion", <u>Human Gene Therapy</u> , 6:1343-1353, October 1995.

EXAMINER	DATE CONSIDERED
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	#6,203,975	03/2001	Wilson				
	6,265,212	07/24/2001	Fallaux et al.				
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	#WO 95/00655	01/05/95	PCT				
	#2 707 664	01/20/95	France				
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	#WO 97/04119	02/06/97	PCT				
	#WO 97/05255	02/13/97	PCT				

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Form PTO-1449		Docket Number (Optional) <b>3833.9US</b>	Application Number <b>Not yet assigned</b>
<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <i>(Use several sheets if necessary)</i>		Applicant <b>Fallaux et al.</b>	
		Filing Date <b>July 11, 2003</b>	Group Art Unit <b>Unknown</b>
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#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior applications:

Serial No.: 10/219,414

Filed: 8/15/2002

For: STOCKS OF REPLICATION DEFICIENT ADENOVIRUS, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.